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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,433	06/28/2000	Lawrence R. McGee	18781-002710US	6127

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EXAMINER
SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
1625	9

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/606,433	MCGEE ET AL.	
	Examiner	Art Unit	
	D. Margaret Seaman	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This application was filed 28 June 2000 and claims priority to Provisional Application 60/141,672, filed 30 June 1999. Claims 1-54 are before the Examiner and are subject to the following restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-54 (in part), drawn to compounds, compositions and methods of use wherein Ar' is pyridyl, classified in class 546, subclass 210+.

II. Claims 1-54 (in part), drawn to compounds, compositions and methods of use wherein Ar' is quinoline, classified in class 546, subclass 153.

III. Claims 1-54 (in part), drawn to compounds, compositions and methods of use wherein Ar' is naphthylene/phenyl, classified in various classes and subclasses, depending upon a further election of a single disclosed species.

IV. Claims 1-54 (in part), drawn to compounds, compositions and methods of use wherein Ar' is benzothiazole, classified in class 548, subclass 148+.

V. Claims 1-54 (in part), drawn to compounds, compositions and methods of use wherein Ar' is benzimidazole, classified in class 548, subclass 300.1+.

VI. Claims 1-54 (in part), drawn to compounds, compositions and methods of use wherein Ar' is isoquinoline, classified in class 546, subclass 141+.

VII. Claims 1-54 (in part), drawn to compounds, compositions and methods of use wherein Ar' is benzoxazole, classified in class 548, subclass 240+.

VIII. Claims 1-54 (in part), drawn to compounds, compositions and methods of use wherein Ar' is other than in groups I-VII plus an election of a single disclosed species, classified in various classes and subclasses.

3. The inventions are distinct, each from the other because of the following reasons:

Unpatentability of the group I compounds/compositions/methods of use would not necessarily imply unpatentability of the group II-VIII compounds/ compositions/ methods of use because the compounds/compositions/methods are so divergent that a reference providing a 35 U.S.C. §102(b) rejection on a member of one group would not render a member of the other groups obvious under 35 U.S.C. §103. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant's election with traverse of group IV in Paper No. 8, dated 15 October 2001 is acknowledged. The traversal is on the ground(s) that there is no burdensome search. This is not found persuasive because the different groups of the restriction can

be searched in classes 514, 540, 544, 546, 548, 549 and 560+. This is a burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 46-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-54 are ambiguous due to the claims being multiply dependent claims. Specifically, claims 46-47 are multiply dependent claims. Claims 48-54 are dependent from claims 46-47. Correction is required.

Claim 52 is ambiguous due to the claim being drawn to "hypercholesterolemia and other lipid-mediated diseases". It is suggested that the claim be rewritten to be drawn to specific diseases or conditions and not "other" diseases.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 47-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, it is not seen where the instant specification enables the ordinary artisan to use the instant invention to modulate the conditions associated with metabolic or inflammatory disorders. How associated with metabolic or inflammatory disorders must a disorder be before it can be treated? How are the diseases/conditions modulated? Are these conditions treated or just modulated? The specification is not clear to this. Due to this, the ordinary artisan would not be enabled by the instant specification to use the instant invention.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-54 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Heinz (US Patent #5,814,646), Reel (US Patent #5,624,937) and Cox (US Patents #4,851,419 and $4,900,751).

Heinz discloses RN 190331-20-5 and teaches a markush of formula I that anticipates the instant claims. Reel teaches a markush of formula I and discloses compounds such as RN 190331-20-5 that anticipate the instant claims. Cox teaches a markush of formula I (see abstract) and discloses compounds such as RN 112903-43-2.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on 703-308-2439. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms
November 27, 2001